

(19) World Intellectual Property Organization  
International Bureau



PCT



(43) International Publication Date  
8 September 2006 (08.09.2006)

(10) International Publication Number  
**WO 2006/093975 A2**

(51) International Patent Classification: **Not classified**

(21) International Application Number:  
PCT/US2006/007114

(22) International Filing Date:  
28 February 2006 (28.02.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
11/070,863 1 March 2005 (01.03.2005) US  
11/070,846 1 March 2005 (01.03.2005) US

(71) Applicant (for all designated States except US): **USGI MEDICAL INC.** [US/US]; 1140 Calle Cordillera, San Clemente, California 92673 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **VAUGHAN, Robert, A.** [US/US]; 2851 Rancho De Linda, Laguna Niguel, California 92677 (US). **LAM, Cong, C.** [US/US]; 74 Stanford Court, Irvine, California 92612 (US). **EWERS, Richard, C.** [US/US]; 1437 West Malvern, Fullerton, California 92833 (US). **SAADAT, Valid** [US/US]; 12679 Kane Drive, Saratoga, California 95070 (US).

(74) Agent: **BAGADE, Sanjay, S.**; Levine Bagade LLP, 2483 Bayshore Road, Suite 100, Palo Alto, CA 94303 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AB, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LE, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

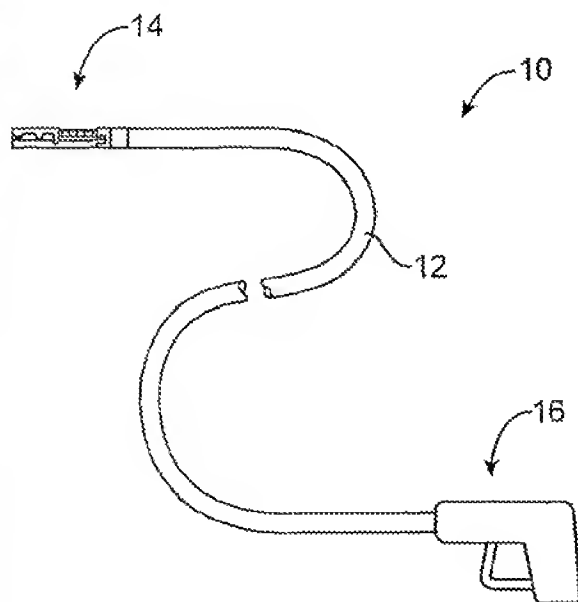
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **TISSUE MANIPULATION AND SECUREMENT SYSTEM**



(57) Abstract: Tissue manipulation and securement systems are described herein. A tissue manipulation assembly is pivotably coupled to the distal end of a tubular member and has a lower jaw member and an upper jaw member pivotably coupled to the lower jaw member. A reconfigurable launch tube is also pivotably coupled to the upper jaw member and is used to urge the jaw members from a low-profile configuration to an open configuration for receiving tissue. The tissue manipulation assembly may be advanced through a shape-lockable endoscopic device, a conventional endoscope, or directly by itself into a patient. A second tool can be used in combination with the tissue manipulation assembly to engage tissue and manipulate the tissue in conjunction with the tissue manipulation assembly.

WO 2006/093975 A2

## TISSUE MANIPULATION AND SECUREMENT SYSTEM

### BACKGROUND OF THE INVENTION

[0001] Field of the Invention. The present invention relates to methods and apparatus for manipulating and/or securing tissue. More particularly, the present invention relates to methods and apparatus for manipulating and/or securing tissue endoluminally, for instance, to form and/or secure tissue folds or to approximate regions of tissue, etc.

[0002] A number of surgical techniques have been developed to treat various gastrointestinal disorders. One such example of a pervasive disorder is morbid obesity. Conventional surgical treatment for morbid obesity typically includes, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0003] Furthermore, the sutures or staples that are often used in surgical procedures for gastrointestinal disorders typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen, for instance, includes four tissue layers, where the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer, and where the serosa layer is the outer-most tissue layer.

[0004] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the

muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intra-operatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

5 [0005] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition known as a plication. Another method involves  
10 manually creating sutures for securing the plication.

[0006] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the  
15 treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0007] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication  
20 will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally.

25 [0008] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

#### BRIEF SUMMARY OF THE INVENTION

30 [0009] An example of a tool which may be utilized for endoluminally accessing tissue may generally comprise a flexible catheter or tubular body which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously,

laparoscopically, etc. The tubular body may be configured to be torqueable such that when a control handle is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along the flexible body such that the distal end of body is advanced, withdrawn, or rotated in a corresponding manner.

5 [0010] A tissue manipulation assembly may be located at the distal end of the tubular body and is generally used to contact and form tissue folds, as mentioned above. The tissue manipulation assembly may be connected to the distal end of the tubular body via a pivotable coupling and a lower jaw member may extend distally from the pivotable coupling with an upper jaw member, in this example, pivotably coupled to the lower jaw member via a jaw  
10 pivot. The location of the jaw pivot may be positioned at various locations along the lower jaw depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., on the surface or surfaces of the jaw members to  
15 facilitate the adherence of tissue therebetween.

[0011] A launch tube may extend from the handle, through tubular body, and distally from the end of tubular body where a distal end of the launch tube is pivotally connected to the upper jaw member at a pivot. A distal portion of the launch tube may be pivoted into position within a channel or groove defined in upper jaw member to facilitate a low-profile  
20 configuration of the tissue manipulation assembly. When articulated, either via the launch tube or other mechanism, the jaw members may be urged into an open configuration to receive tissue in the jaw opening between the jaw members.

[0012] In operation, a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus. Such an endoscopic assembly may  
25 generally comprise an endoscopic device which may have a distal portion which may be articulated and steered to position its distal end anywhere within the stomach. Once desirably configured, the assembly may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered therethrough.

30 [0013] The tissue manipulation assembly may be delivered into the patient while in a low-profile configuration, e.g., transorally, through the shape-lockable endoscopic assembly, through an endoscope, an endoscopic device, or directly. Once desirably positioned, the

launch tube may be urged proximally via its proximal end at handle. Because the jaw assembly pivot and the relative positioning of the upper jaw pivot along lower jaw member and launch tube pivot along upper jaw member, the proximal movement of the launch tube may effectively articulate upper jaw into an expanded jaw configuration. Proximally urging the launch tube may also urge the lower jaw member to pivot about the assembly pivot and form an angle relative to a longitudinal axis of the tubular body. The opening of the upper jaw relative to the lower jaw creates a jaw opening for grasping or receiving tissue.

Moreover, the tissue manipulation assembly may also include a stop located adjacent to the jaw assembly pivot or within the pivot itself.

- 10 [0014] A second tool for initially engaging the tissue region of interest may also be deployed and utilized to engage the tissue and to position the engaged tissue between the jaws of the jaw assembly. Any number of tools may be used in combination with the tissue manipulation assembly. Once the tissue has been engaged between the jaw members, a needle assembly may be urged through the launch tube to pierce through the grasped tissue.
- 15 Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- 20 [0015] Fig. 1A shows a side view of one variation of a tissue manipulation assembly having a flexible body and a handle.

[0016] Fig. 1B illustrates a detail side view of a tissue manipulation assembly in a low-profile configuration connected to the distal end of the tubular body via a pivotable coupling.

- [0017] Figs. 2A to 2C illustrate a method for articulating the tissue manipulation assembly from a low-profile configuration to an opened configuration and to a closed jaw configuration for clamping upon tissue, respectively.
- 25

[0018] Figs. 3A and 3B show detail perspective views of the tissue manipulation assembly in an open and clamped configuration, respectively.

[0019] Fig. 4 shows an assembly view of how a needle deployment assembly may be introduced through a handle and tubular body of the tissue manipulation assembly.

- 30 [0020] Fig. 5A shows a detailed assembly view of the needle deployment assembly from Fig. 4.

[0021] Fig. 5B shows an exploded assembly view of the needle deployment assembly from Fig. 5A.

[0022] Fig. 6 illustrates one example in which a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus with a tissue manipulation assembly advanced through a first lumen and a tissue engagement member advanced through a second lumen.

[0023] Fig. 7 illustrates a tissue manipulation assembly and examples of various tools which may be used in combination with the tissue manipulation assembly.

[0024] Figs. 8A to 8D illustrate an example for performing an endoluminal tissue manipulation and securement procedure utilizing a tissue manipulation assembly in combination with a separate tissue grasping tool within, e.g., a patient's stomach.

[0025] Fig. 9A shows one variation where a single tissue fold may be secured between tissue anchors using the tissue manipulation assembly.

[0026] Fig. 9B shows another variation where two or more tissue folds may be secured between tissue anchors using the tissue manipulation assembly.

[0027] Figs. 10A and 10B illustrate a variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a number of reinforcement members or bars may be positioned along the launch tube to increase its column strength.

[0028] Figs. 11A and 11B illustrate another variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a pull wire may be routed through the launch tube to facilitate articulation of the launch tube and/or jaw assembly.

[0029] Fig. 12 illustrates yet another variation of the tissue manipulate assembly which may also utilize a pull wire connected directly to the launch tube.

## DETAILED DESCRIPTION OF THE INVENTION

[0030] In manipulating tissue or creating tissue folds, a having a distal end effector may be advanced endoluminally, e.g., transorally, transgastrically, etc., into the patient's body, e.g., the stomach. The tissue may be engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body. Examples of creating and forming tissue plications may be seen in further detail in U.S. Pat. App. Serial

No. 10/955,245 filed September 29, 2004, which has been incorporated herein by reference above, as well as U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

5 [0031] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned via an endoscopic apparatus for contacting a tissue wall of the gastrointestinal lumen, creating one or more tissue folds, and deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

10 [0032] An illustrative side view of one example of a tool which may be utilized for endoluminally accessing tissue is shown in Fig. 1A, which shows assembly 10. The assembly 10 generally comprises a flexible catheter or tubular body 12 which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body 12 may be configured to be torqueable  
15 through various methods, e.g., utilizing a braided tubular construction, such that when handle 16 is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along body 12 such that the distal end of body 12 is advanced, withdrawn, or rotated in a corresponding manner.

[0033] Tissue manipulation assembly 14 is located at the distal end of tubular body 12 and  
20 is generally used to contact and form tissue folds, as mentioned above. Fig. 1B shows an illustrative detail side view in which tissue manipulation assembly 14 may be seen connected to the distal end of tubular body 12 via a pivotable coupling 18. Lower jaw member 20 extends distally from the pivotable coupling 18 and upper jaw member 22, in this example, may be pivotably coupled to lower jaw member 20 via jaw pivot 26. The location of jaw  
25 pivot 26 may be positioned at various locations along lower jaw 20 depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members 20, 22 may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., 24 on the surface or surfaces of the jaw members 20, 22 facing one another to  
30 facilitate the adherence of tissue between the jaw members 20, 22.

[0034] Launch tube 28 may extend from handle 16, through tubular body 12, and distally from the end of tubular body 12 where a distal end of launch tube 28 is pivotally connected to

upper jaw member 22 at launch tube pivot 30. A distal portion of launch tube 28 may be pivoted into position within a channel or groove defined in upper jaw member 22, to facilitate a low-profile configuration of tissue manipulation assembly 14. When articulated, either via launch tube 28 or other mechanism, as described further below, jaw members 20, 22 may be urged into an open configuration to receive tissue in jaw opening 32 between the jaw members 20, 22.

[0035] Launch tube 28 may be advanced from its proximal end at handle 16 such that the portion of launch tube 28, which extends distally from body 12, is forced to rotate at hinge or pivot 30 and reconfigure itself such that the exposed portion forms a curved or arcuate shape that positions the launch tube opening perpendicularly relative to upper jaw member 22. Launch tube 28, or at least the exposed portion of launch tube 28, may be fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

[0036] Figs. 2A to 2C illustrate one method for articulating a tissue manipulation assembly into an opened and closed configuration. As shown in Fig. 2A, the assembly may be delivered into a patient while in a low-profile configuration 40, e.g., transorally, through an endoscope, an endoscopic device, or directly. Once desirably positioned, launch tube 28 may be urged proximally via its proximal end at handle 16. Because of jaw assembly pivot 18 and the relative positioning of upper jaw pivot 26 along lower jaw member 20 and launch tube pivot 30 along upper jaw member 22, the proximal movement of launch tube 28 may effectively articulate upper jaw 22 into an expanded jaw configuration 42, as shown in Fig. 2B. Proximally urging launch tube 28 may also urge lower jaw member 20 to pivot about assembly pivot 18 and form an angle,  $\alpha$ , relative to a longitudinal axis of tubular body 12. The opening of upper jaw 22 relative to lower jaw 20 creates jaw opening 32 for grasping or receiving tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to jaw assembly pivot 18 or within the pivot 18 itself.

[0037] Once launch tube 28 has been urged proximally, it may be locked into place thus locking the jaw configuration as well. Moreover, having the launch tube 28 articulate the jaw members 20, 22 in this variation eliminates the need for a separate jaw articulation and/or locking mechanism. Once the tissue has been pulled or manipulated between jaw members 20, 22, launch tube 28 may be pushed distally to actuate the jaw members 20, 22 into a closed, grasping configuration 48, as shown in Fig. 2C, for engagement with the tissue. As



launch tube 28 is urged distally through body 12, lower jaw member 20 may be maintained at the angle,  $\alpha$ , relative to the tissue to further facilitate manipulation of the grasped tissue.

[0038] Launch tube 28 may further define a flexible portion 44 distally of a rigid portion 46. Although launch tube 28 may be fabricated from different materials having differing flexibilities, it may also be fabricated from a single material, as mentioned above, where the flexible portion 44 may be configured, e.g., by slotting, to allow for bending of the launch tube 28 in a plane to form a single curved or arcuate section while the rigid section 46 may extend at least partially into tubular body 12 to provide column strength to launch tube 28 while it is urged distally upon upper jaw member 22 and upon any tissue engaged thereby, as seen in the Fig. 2C.

[0039] Once the tissue has been engaged between jaw members 20, 22, a needle assembly may be urged through handle 16 and out through launch tube 28. The needle assembly may pass through lower jaw member 20 via needle assembly opening 50 defined in lower jaw member 20 to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue, as described in further detail in U.S. Pat. App. Serial No. 10/955,245, which has been incorporated by reference above.

[0040] Figs. 3A and 3B show detail perspective views of the tissue manipulation assembly. As shown in Fig. 3A, lower jaw member 20 and upper jaw member 22 may be seen in its open configuration 42 when the launch tube has been urged proximally. Launch tube channel 52 may also be seen defined within upper jaw member 22 for providing a space for positioning the launch tube when in the low-profile configuration. Also shown is needle assembly opening 50 defined within lower jaw member 20 for passage of the needle assembly therethrough. Fig. 3B shows the assembly in its closed jaw configuration where the launch tube has been urged distally in which it rotates about launch tube pivot 30 such that the opening of the launch tube becomes perpendicular relative to the jaw members 20, 22.

[0041] Although one particular variation of the jaw members 20, 22 is shown, this is not intended to be limiting in jaw member configuration or operation. Other variations may include various placement of the jaws relative to one another, alternative configurations for articulating the jaw members, alternative configurations for the launch tube placement, etc. Other variations are intended to be within the scope of this disclosure.

[0042] As mentioned above, a needle deployment assembly 60 may be deployed through the assembly 10 by introducing needle deployment assembly 60 into the handle 16 and through tubular body 12, as shown in the assembly view of Fig. 4, such that the needle assembly 66 is advanced from the launch tube and into or through approximated tissue. Once the needle assembly 66 has been advanced through the tissue, the anchor assembly 68 may be deployed or ejected. Anchor assembly 68 is normally positioned within the distal portion of tubular sheath 64 which extends from needle assembly control or housing 62. Once the anchor assembly 68 has been fully deployed from sheath 64, the spent needle deployment assembly 60 may be removed from assembly 10 and another needle deployment assembly may be introduced without having to remove assembly 10 from the patient. The length of sheath 64 is such that it may be passed entirely through the length of tubular body 12 to enable the deployment of needle assembly 66 into and/or through the tissue.

[0043] Fig. 5A shows a detailed assembly view of the needle deployment assembly 60 from Fig. 4. In this variation, elongate and flexible sheath or catheter 64 may extend removably from needle assembly control or housing 62. Sheath or catheter 64 and housing 62 may be interconnected via interlock 70 which may be adapted to allow for the securement as well as the rapid release of sheath 64 from housing 62 through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. Needle body 72, which may be configured into any one of the variations described above, may extend from the distal end of sheath 64 while maintaining communication between the lumen of sheath 64 and needle opening 74.

[0044] Elongate pusher 76 may comprise a flexible wire or hypotube which is translationally disposed within sheath 64 and movably connected within housing 62. A proximally-located actuation member 78 may be rotatably or otherwise connected to housing 62 to selectively actuate the translational movement of elongate pusher 76 relative to sheath 64 for deploying the anchors from needle opening 74. Anchor assembly 68 may be seen positioned distally of elongate pusher 76 within sheath 64 for deployment from sheath 64. Needle assembly guides 80 may also be seen protruding from housing 62 for guidance through the locking mechanism described above. Fig. 5B shows an exploded assembly view of the needle deployment assembly 60 from Fig. 5A. As seen, sheath 64 may be disconnected from housing 62 via interlock 70 to reveal the elongate pusher 76 connected to housing 62 and the distal and proximal anchors 82, 84, respectively, of anchor assembly 68.

[0045] With respect to the anchor assemblies, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, the tissue anchor variations may also include "T"-type anchors while other variations may include reconfigurable "basket"-type anchors, which may generally comprise a number of

5 configurable struts or legs extending between at least two collars or support members or reconfigurable mesh structures extending between the two collars. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. Furthermore, the

10 different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0046] Other variations for the needle assemblies and for the anchors are described in further detail in U.S. Pat. App. Serial No. 10/955,245, which has been incorporated by

15 reference above.

[0047] In operation when manipulating and securing tissue within a patient's body, a separate elongate shaft having a tool on or near the distal end of the shaft may be utilized in conjunction with the tissue manipulation assembly 14. Such tools are generally utilized in endoluminal procedures where the tools are delivered through an endoscope. Generally,

20 several different tools may be utilized for performing a procedure endoluminally.

[0048] As illustrated in Fig. 6, one such example is shown in which a shape-lockable endoscopic assembly 90 may be advanced into a patient's stomach S per-orally and through the esophagus E. Such an endoscopic assembly 90 may generally comprise an endoscopic device which may have a distal portion which may be articulated and steered to position its

25 distal end anywhere within the stomach S. Once desirably configured, assembly 90 may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered through the assembly 90. Shape-lockable assembly 90 and its variations are described in further detail in U.S. Pat. App. Serial No. 10/734,562 filed December 12, 2003, which is incorporated herein by reference in

30 its entirety.

[0049] Shape-lockable assembly 90 may be generally comprised of shape-lockable endoscopic body 92 having an articulatable distal portion 96. The endoscopic body 92 may

define at least first and second lumens 98, 100, respectively, through the endoscopic body 92 through which one or more tools may be deployed into the stomach S. Additional lumens may be provided through shape-lockable endoscopic body 92, such as a visualization lumen 101, through which an endoscope may be positioned to provide visualization of the region of tissue. Alternatively, an imager such as a CCD imager or optical fibers may be provided in lumen 101 to provide visualization. An optional thin wall sheath 94 may be disposed through the patient's mouth, esophagus E, and possibly past the gastroesophageal junction GEJ into the stomach S. Shape-lockable body 92 may be advanced through esophagus E (and through sheath 94, if utilized) and into stomach S while disposed in a flexible state.

[0050] Distal steerable portion 96 of endoscopic body 92 may be then articulated to an orientation, e.g., whereby distal portion 96 facilitates engagement of tissue near and/or inferior to the patient's gastroesophageal junction GEJ. Accordingly, distal steerable portion 96 may comprise a number of steering features, as described in further detail in U.S. Pat. App. Serial No. 10/734,562, incorporated above. With distal steerable portion 96 disposed in a desired configuration or orientation, endoscopic body 92 may be reversibly shape-locked to a rigid state such that the endoscopic body 92 maintains its position within the stomach S. Various methods and apparatus for rigidizing endoscopic body 92 along its length are also described in further detail in U.S. Pat. App. Serial No. 10/734,562, incorporated above.

[0051] Fig. 6 shows tissue manipulation assembly 14 having been advanced through first lumen 98 and a tissue engagement member 102 positioned upon flexible shaft 104 advanced through second lumen 100. As the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, tissue engagement member 102 may be advanced into contact with the tissue and preferably engages the tissue F such that when the tissue engagement member 102 is pulled proximally to draw the engaged tissue F between the jaw members 20, 22 of tissue manipulation assembly 14, at least the muscularis tissue layer and the serosa layer is drawn into tissue manipulation assembly 14.

[0052] As tissue manipulation assembly 14 may be utilized to grasp and secure the engaged tissue, any number of tools may be utilized with tissue manipulation assembly 14, e.g., through shape-lockable endoscopic body 92, to engage and manipulate the tissue of interest relative to tissue manipulation assembly 14. Fig. 7 illustrates tissue manipulation assembly

14 upon flexible body 12 with handle 16 and examples of various tools which may be used in combination with tissue manipulation assembly 14.

[0053] Turning to Fig. 7, one example of a tool utilizable in combination with tissue manipulation assembly 14 is shown in tissue engagement member 102 as a tissue piercing helix or corkscrew structure upon flexible shaft 104 (as shown in Fig. 6). Tissue engagement member 102 may be rotated about its longitudinal axis to engage the tissue of interest by rotating handle 106 located on the proximal end of flexible shaft 104. Alternatively, a tool having aggressive tissue graspers 108 positioned upon flexible shaft 110 and articulatable via handle 112 may be utilized in combination with tissue manipulation assembly 14. Another alternative tool may be tissue graspers 114 positioned upon flexible shaft 116 and articulatable via handle 118. Tissue graspers 114 may have atraumatic grasping surfaces. In yet another alternative, an endoscope 122 having optical fibers or imager 120 may be utilized for providing visualization. Endoscope 122 may be articulated via handle 124 at its proximal end.

[0054] The examples of the various tools as shown and described are intended merely to be illustrative of the range of tools which may be usable with assembly 14 and are not intended to be limiting in any manner. Any number of other tools may be accordingly utilized and are intended to be within the scope of this disclosure.

[0055] An example of performing an endoluminal tissue manipulation and securement procedure utilizing tissue manipulation assembly 14 in combination with a separate tissue grasping tool within, e.g., a patient's stomach, is illustrated in Figs. 8A to 8D. As shown in Fig. 8A, once shape-lockable endoscopic body 92 has been introduced into the patient, e.g., trans-orally, trans-anally, percutaneously, etc., and desirably positioned relative to a tissue region of interest 130, endoscopic body 92 may be rigidized to maintain its configuration within the patient body. Alternatively, it may be left in a flexible state during the procedure.

[0056] The tissue region of interest 130 as well as the procedure may be visualized through visualization lumen 101 or a separate imager, as described above. In either case, tissue manipulation assembly 14 and tissue engagement member 102 may be advanced distally out from endoscopic body 92 through their respective lumens 98, 100. Tissue engagement member 102 may be advanced into contact against the tissue surface, as shown in Fig. 8A, and then rotated via its proximal handle until the tissue is engaged. The engaged tissue F may be pulled proximally relative to endoscopic body 92 and tissue manipulation assembly

14 may be actuated via its proximally located handle into an open expanded jaw configuration for receiving the engaged tissue F, as shown in Fig. 8B.

[0057] Alternatively, once the tissue F has been engaged, tissue manipulation assembly 14 may be advanced distally in its open configuration onto the engaged tissue. In yet another variation, tissue engagement member 102 may be omitted entirely and tissue manipulation assembly 14 may be utilized alone to grasp onto the tissue region of interest 130. In yet another alternative, a second tissue manipulation assembly may be used in combination with tissue manipulation assembly 14.

[0058] Turning back to Fig. 8B, tissue manipulation assembly 14 may be articulated to receive the engaged tissue F. As shown in Fig. 8C, once engaged tissue F is positioned between jaw members 20, 22, the launch tube may be urged proximally to actuate upper jaw member 22 to grasp or clamp upon the tissue F. Tissue engagement member 102 may be retracted from the tissue F or it may be left within the tissue while tissue manipulation assembly engages and secures the tissue F.

[0059] Fig. 8D shows a partial cross-sectional view of the tissue F while engaged to tissue manipulation assembly 14. Tissue engagement member 102 has been omitted from this view only for the sake of clarity. As mentioned above, member 102 may be left remaining in the tissue F, disengaged from tissue F, or disengaged and removed entirely from endoscopic body 92, if so desired, and another tool may be advanced through lumen 100 to facilitate the procedure. Once jaw members 20, 22 have been actuated to clamp or grasp upon tissue F by the launch tube, the launch tube may be automatically positioned into its anchor deployment configuration. The needle assembly may then be urged via manipulation from its proximal end at handle 16 through the launch tube to pierce preferably through a dual serosa layer through engaged tissue F and past lower jaw member 20. As described above, the engaged tissue F positioned between the jaw members 20, 22 is desirably engaged such that the needle body 72, when urged through the tissue F, is disposed through the muscularis and/or serosa layers of the engaged tissue F. Once needle body 72 has passed through tissue F, one or more expandable tissue anchors may be ejected from needle body 72 through needle opening 74.

[0060] Because needle body 72 may penetrate the tissue wall twice, it exits within the body lumen if utilized within, e.g., the stomach, thus reducing the potential for injury to surrounding organs. As described above, needle body 72 may define needle lumen or

opening 74 through which expandable an anchor, e.g., distal anchor 82 and/or proximal anchor 84, may be situated during deployment and positioning of the assembly. A single suture or flexible element 132 (or multiple suture elements) may connect distal anchor 82 and proximal anchor 84 to one another and end in terminal loop 134. For instance, element 132 may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0061] Once distal anchor 82 has been ejected, needle body 72 may be urged proximally back through tissue F, where proximal anchor 84 may then be ejected from needle body 72 with suture 132 still connecting the two anchors 82, 84 through tissue F. Alternatively, tissue manipulation assembly 14, with suture 132 still depending therefrom, may be disengaged from tissue F and the procedure may be repeated at a second region of tissue where proximal anchor 84 may then be ejected.

[0062] Fig. 9A shows one variation where a single fold F may be secured between proximal anchor 82 and distal anchor 84. With both anchors 82, 84 disposed externally of the launch tube and suture 132 connecting the two, proximal anchor 84 may be urged into contact against tissue F. As the anchors are urged against tissue fold F, distal anchor 82 or a portion of suture 132 may be configured to provide any number of directionally translatable locking mechanisms 136 which provide for movement of an anchor along suture 132 in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture 132.

[0063] Fig. 9B shows another variation where a at least two folds F<sub>1</sub> and F<sub>2</sub> may be secured between proximal anchor 82 and distal anchor 84. After the anchors have been ejected from needle body 72, the anchors may be approximated towards one another over suture 132 thus bringing folds F<sub>1</sub> and F<sub>2</sub> towards one another. Although a single tissue fold and a dual fold are shown in these examples, any number of folds or tissue ridges may be created using the tools disclosed herein. Moreover, these examples are merely intended to be illustrative and not limiting in any way. In either case, it may be generally desirable to form the tissue folds such that serosa-to-serosa contact 138 occurs between the layers of secured tissue, although this may not be necessary.

[0064] Various examples of cinching devices and methods which may be utilized with the tools and devices herein are described in further detail in U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated herein above.

[0065] In using the launch tube as a jaw actuation mechanism, other variations of the launch tube may be utilized to ensure sufficient strength and force transmission in tissue manipulation assembly 14 for jaw member actuation. One such example is shown in the perspective view of Fig. 10A, which shows launch tube 44 having a number of reinforcement members or bars 140 aligned along one or both sides of the launch tube to provide for additional column strength. Each of the reinforcement members 140 may be pivotally attached to launch tube 44 via pivot members 144 rotatably secured within pivot channels 142, as seen in the launch tube cross-section in Fig. 10B. Moreover, each of the pivot members 144 may define cooperating adjacent members relative to one another while maintaining contact to allow for the transmission of force between the members 144. Pivot members 144 may be positioned along the length of the exposed launch tube or a portion of the launch tube; moreover, a single side of the launch tube may have pivot members 144 attached thereto. Alternatively, rather than utilizing pivot members, portions of the launch tube itself may be simply thickened to increase its column strength and force transmission capabilities.

[0066] In another variation, as shown in Fig. 11A and the launch tube cross-section in Fig. 11B, a pull wire 152 may be routed through tubular body 12 and launch tube 44 through a pull wire lumen 150 to provide a launch tube and jaw actuation mechanism separate from the launch tube actuation itself. Pull wire 152 may be manipulated via its proximal end at handle 16 by pulling or pushing pull wire 152 to actuate launch tube 44 and/or jaw members 20, 22. Alternatively, pull wire 152 may be routed through tubular body 12 and connected directly to launch tube 44 at pull wire attachment point 154 rather than routing it through the launch tube. Again, manipulation of pull wire 152 may be utilized to articulate the launch tube configuration as well as jaw member articulation.

[0067] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Moreover, although specific configurations and applications may be shown, it is intended that the various features may be utilized in various combinations and in various types of procedures as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.



WHAT IS CLAIMED IS:

- 1           1.       A tissue manipulation system, comprising:  
2               a tissue grasping tool pivotably coupled to a distal end of an elongate member  
3               and adapted to be advanced endoluminally into a body lumen; and  
4               a tissue engagement device having a distal end effector adapted to reversibly  
5               engage tissue and further adapted to be positioned endoluminally within the body lumen  
6               adjacent to the tissue grasping tool.
- 1           2.       The system of claim 1 wherein the tissue grasping tool comprises a  
2               first jaw member pivotably coupled to the distal end of the elongate member, a second jaw  
3               member pivotably coupled along the first jaw member, and a launch tube member adapted to  
4               urge the first and second jaw members between a low-profile delivery configuration and an  
5               expanded grasping configuration.
- 1           3.       The system of claim 2 wherein at least one of the first and second jaw  
2               members comprise protrusions for facilitating engagement onto the tissue.
- 1           4.       The system of claim 2 further comprising a stop for limiting a pivoting  
2               motion of the first jaw member.
- 1           5.       The system of claim 2 wherein a distal end of the launch tube member  
2               is pivotably coupled to the second jaw member.
- 1           6.       The system of claim 2 wherein the launch tube member comprises a  
2               distally located flexible portion.
- 1           7.       The system of claim 6 wherein the launch tube member further  
2               comprises a rigid portion proximally of the flexible portion.
- 1           8.       The system of claim 2 wherein the first and second jaw members are  
2               adapted to reconfigure into the expanded grasping configuration when the launch tube is  
3               urged proximally.
- 1           9.       The system of claim 1 wherein the distal end effector comprises a  
2               helical member having a tissue piercing tip.

1                   10.     The system of claim 1 wherein the distal end effector comprises a  
2     grasper for reversibly engaging the tissue.

1                   11.     A tissue manipulation system, comprising:  
2                   an endoscopic device having a flexible body with a steerable distal section,  
3     wherein the flexible body is adapted to be rigidized to maintain an arbitrary shape;  
4                   a tissue grasping tool pivotably coupled to a distal end of an elongate member  
5     and adapted to be advanced through the endoscopic device; and  
6                   a tissue engagement device having a distal end effector adapted to reversibly  
7     engage tissue and further adapted to be advanced through the endoscopic device.

1                   12.     The system of claim 11 wherein the endoscopic device further defines  
2     a lumen for visualization.

1                   13.     The system of claim 11 wherein the endoscopic device defines at least  
2     a first and a second lumen therethrough.

1                   14.     The system of claim 13 wherein the tissue grasping tool is adapted to  
2     be advanced through the first lumen within the endoscopic device.

1                   15.     The system of claim 13 wherein the tissue engagement device is  
2     adapted to be advanced through the second lumen within the endoscopic device.

1                   16.     The system of claim 11 wherein the tissue grasping tool comprises a  
2     first jaw member pivotably coupled to the distal end of the elongate member, a second jaw  
3     member pivotably coupled along the first jaw member, and a launch tube member adapted to  
4     urge the first and second jaw members between a low-profile delivery configuration and an  
5     expanded grasping configuration.

1                   17.     The system of claim 16 further comprising a needle assembly having a  
2     piercing tip which is adapted to be advanced through the launch tube.

1                   18.     The system of claim 17 further comprising at least two tissue anchors  
2     adapted to be ejected from the needle assembly for securing the engaged tissue therebetween.

1                   19.     A tissue manipulation system, comprising:

2 a tissue grasping tool pivotably coupled to a distal end of an elongate member  
3 and having a first jaw member pivotably coupled to the distal end of the elongate member, a  
4 second jaw member pivotably coupled along the first jaw member, and a launch tube member  
5 adapted to urge the first and second jaw members between a low-profile delivery  
6 configuration and an expanded grasping configuration; and  
7 a tissue engagement device having a helical piercing member on a distal end  
8 of a flexible shaft.

1 20. The system of claim 19 wherein at least one of the first and second jaw  
2 members comprise protrusions for facilitating engagement onto the tissue.

1 21. The system of claim 19 wherein a distal end of the launch tube  
2 member is pivotably coupled to the second jaw member.

1 22. The system of claim 19 wherein the launch tube member comprises a  
2 distally located flexible portion.

1 23. The system of claim 19 wherein the first and second jaw members are  
2 adapted to reconfigure into the expanded grasping configuration when the launch tube is  
3 urged proximally.

1 24. A method of securing tissue within a hollow body organ, comprising:  
2 endoluminally advancing a tissue grasping tool pivotably coupled to a distal  
3 end of an elongate member into the hollow body organ;  
4 reversibly engaging tissue within the hollow body organ with a distal end  
5 effector positioned adjacently to the tissue grasping tool; and  
6 clamping the engaged tissue with the tissue grasping tool.

1 25. The method of claim 24 wherein endoluminally advancing comprises  
2 advancing the tissue grasping tool transesophageally into a stomach.

1 26. The method of claim 24 wherein endoluminally advancing comprises  
2 advancing an endoscopic device having a flexible body with a steerable distal section  
3 transesophageally, wherein the flexible body is adapted to be rigidized to maintain an  
4 arbitrary shape.

1           27.     The method of claim 26 further comprising steering the distal section  
2     within the hollow body organ to a tissue region of interest and rigidizing the endoscopic  
3     device.

1           28.     The method of claim 24 wherein reversibly engaging tissue comprises  
2     rotating a helical piercing member into the tissue and proximally urging the engaged tissue  
3     with the helical piercing member.

1           29.     The method of claim 24 wherein clamping the engaged tissue  
2     comprises urging a launch tube member distally such that an upper and lower jaw member  
3     are urged onto the engaged tissue.

1           30.     The method of claim 24 further comprising securing the engaged tissue  
2     via the tissue grasping tool.

1           31.     A tissue securement apparatus, comprising:  
2             an elongate body having a proximal end, a distal end, and a flexible length  
3     therebetween;  
4             a first jaw member pivotably coupled to the distal end of the elongate member;  
5             a second jaw member pivotably coupled along the first jaw member; and  
6             a launch tube defining a lumen therethrough, the launch tube being slidably  
7     positioned along the elongate body and pivotably coupled to the second jaw member.

1           32.     The apparatus of claim 31 wherein at least one of the first and second  
2     jaw members comprise protrusions for facilitating engagement onto the tissue.

1           33.     The apparatus of claim 31 wherein a distal end of the launch tube  
2     member is pivotably coupled to the second jaw member.

1           34.     The apparatus of claim 31 wherein the launch tube member comprises  
2     a distally located flexible portion.

1           35.     The apparatus of claim 34 wherein the launch tube member further  
2     comprises a rigid portion proximally of the flexible portion.

1           36.     The apparatus of claim 31 wherein the first and second jaw members  
2     are adapted to configure into an expanded configuration when the launch tube is urged  
3     proximally,

1           37.     The apparatus of claim 31 wherein the first and second jaw members  
2     are adapted to configure into a grasping configuration when the launch tube is urged distally.

1           38.     The apparatus of claim 31 wherein the first jaw member defines an  
2     opening for passage of a needle assembly therethrough.

1           39.     The apparatus of claim 31 further comprising a needle assembly  
2     slidably positioned within the launch tube, the needle assembly having a needle body and an  
3     anchor assembly for securing tissue therebetween.

1           40.     The apparatus of claim 31 further comprising a pull wire connected to  
2     a portion of the launch tube for articulating the apparatus about the distal end of the elongate  
3     member.

1           41.     A method of securing tissue within a hollow body organ, comprising:  
2                   endoluminally advancing into a hollow body organ an elongate flexible  
3     member having a first jaw member and a second jaw member in a low-profile configuration  
4     positioned on a distal end of the elongate flexible member;

5                   urging the first jaw member to pivot about the elongate member distal end by  
6     proximally translating a launch tube;

7                   urging the second jaw member to pivot into contact against the first jaw  
8     member by distally translating the launch tube.

1           42.     The method of claim 41 wherein endoluminally advancing comprises  
2     advancing the elongate flexible member transesophageally into a stomach.

1           43.     The method of claim 41 wherein endoluminally advancing comprises  
2     advancing the elongate flexible member through an endoscopic device into the hollow body  
3     organ.

1           44.     The method of claim 43 further comprising rigidizing a length of the  
2     endoscopic device when positioned within the hollow body organ.

1           45.    The method of claim 41 wherein urging the first jaw member to pivot  
2 comprises pivoting the first jaw member such that the first jaw member is angled relative to a  
3 longitudinal axis of the elongate flexible member.

1           46.    The method of claim 41 wherein urging the second jaw member to  
2 pivot comprises rotating the second jaw member against the first jaw member into a clamping  
3 configuration.

1           47.    The method of claim 41 further comprising positioning a portion of  
2 tissue to be secured between the first and second jaw members prior to urging the second jaw  
3 member to pivot into contact.

1           48.    The method of claim 41 further comprising advancing a needle  
2 assembly through the launch tube such that the needle assembly exits the launch tube and  
3 passes through the first jaw member.

1           49.    The method of claim 48 further comprising deploying a first tissue  
2 anchor from the needle assembly.

1           50.    The method of claim 49 further comprising deploying a second tissue  
2 anchor from the needle assembly after disengaging the second jaw member from the first jaw  
3 member.

1           51.    The method of claim 41 further comprising proximally translating the  
2 launch tube to urge the second jaw member away from the first jaw member.

1 / 12

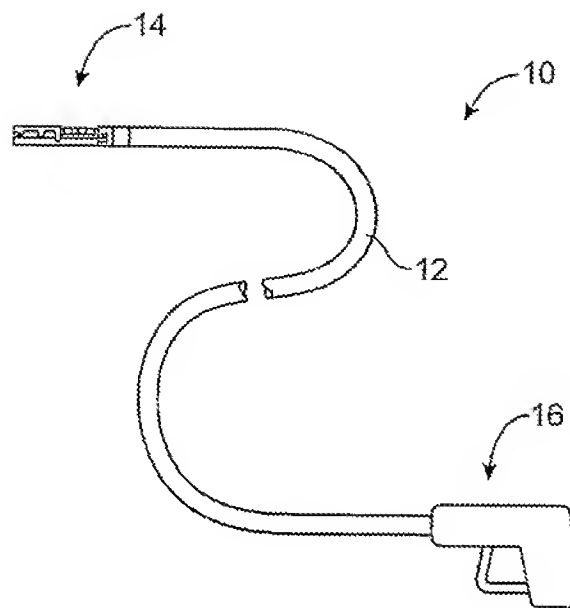


FIG. 1A

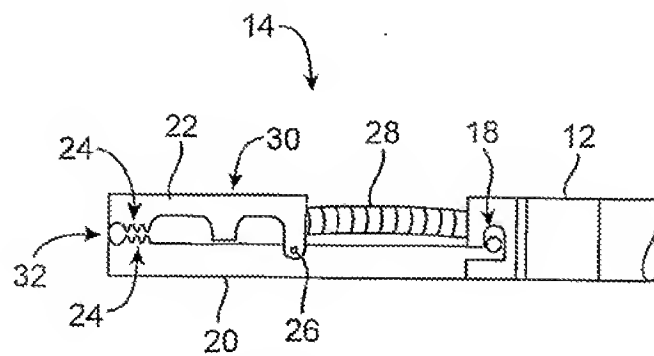


FIG. 1B

2 / 12

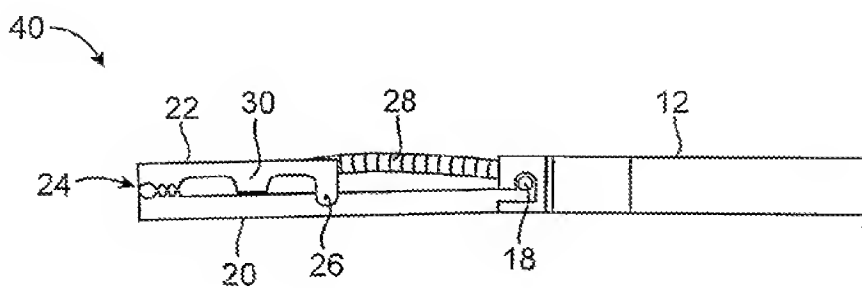


FIG. 2A

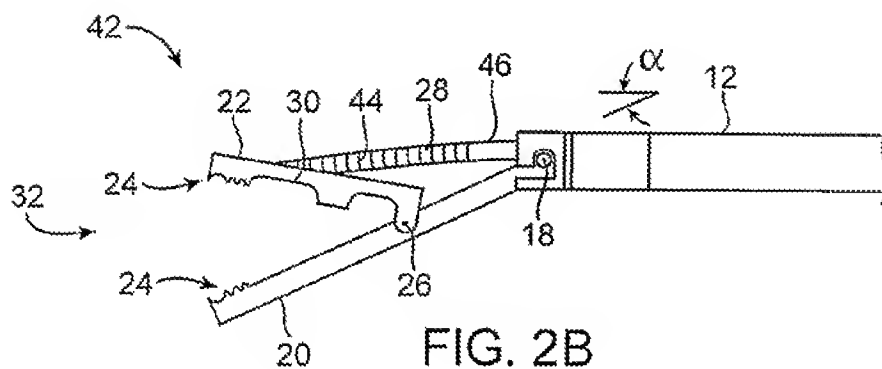


FIG. 2B

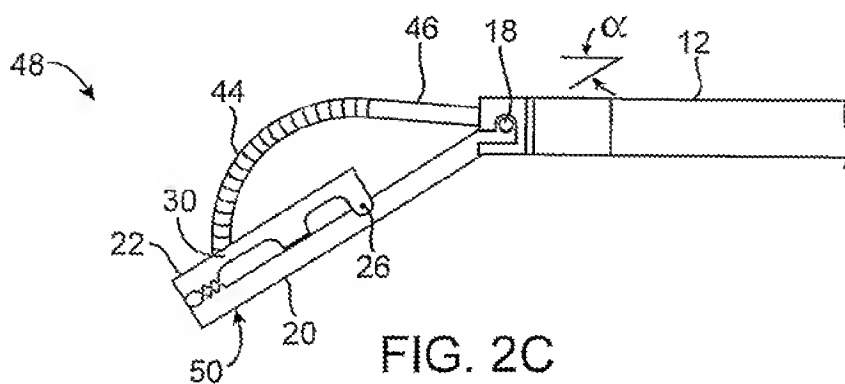


FIG. 2C



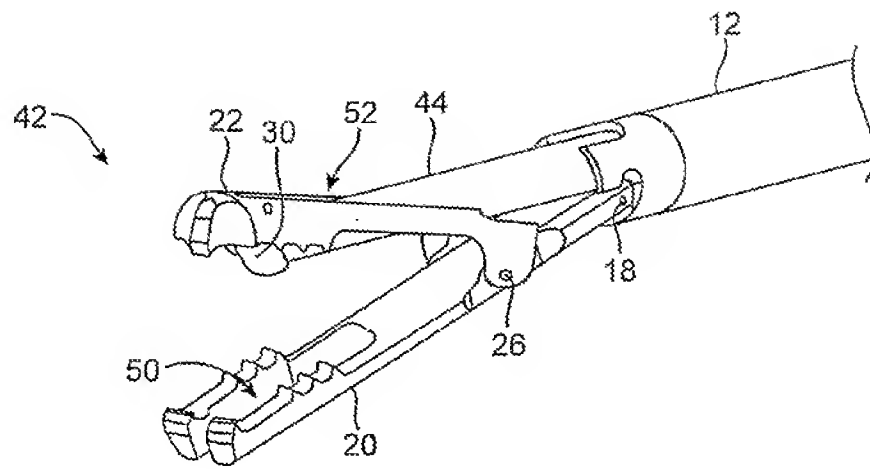


FIG. 3A

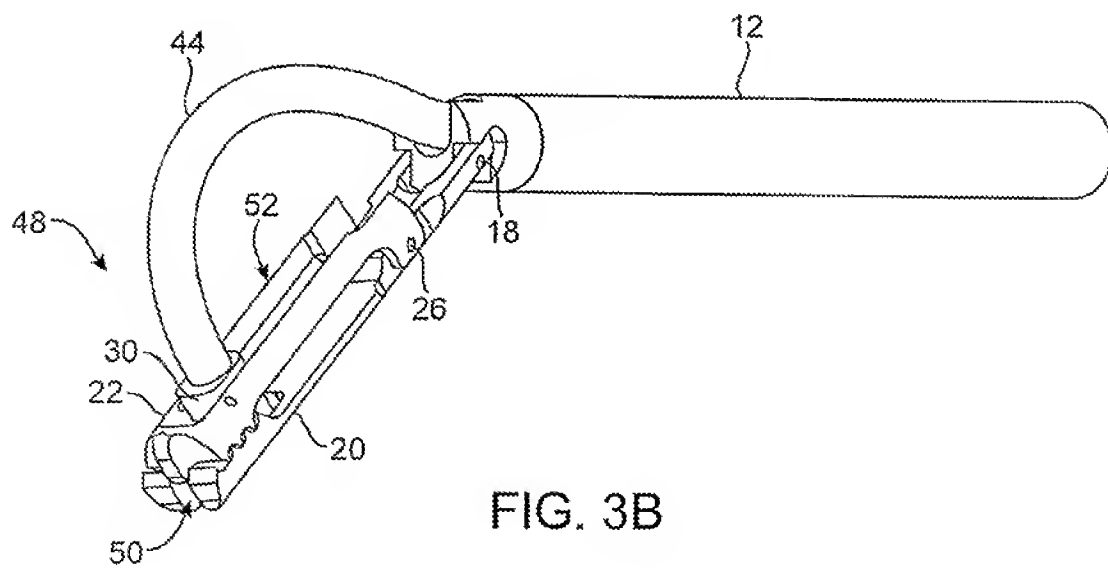


FIG. 3B

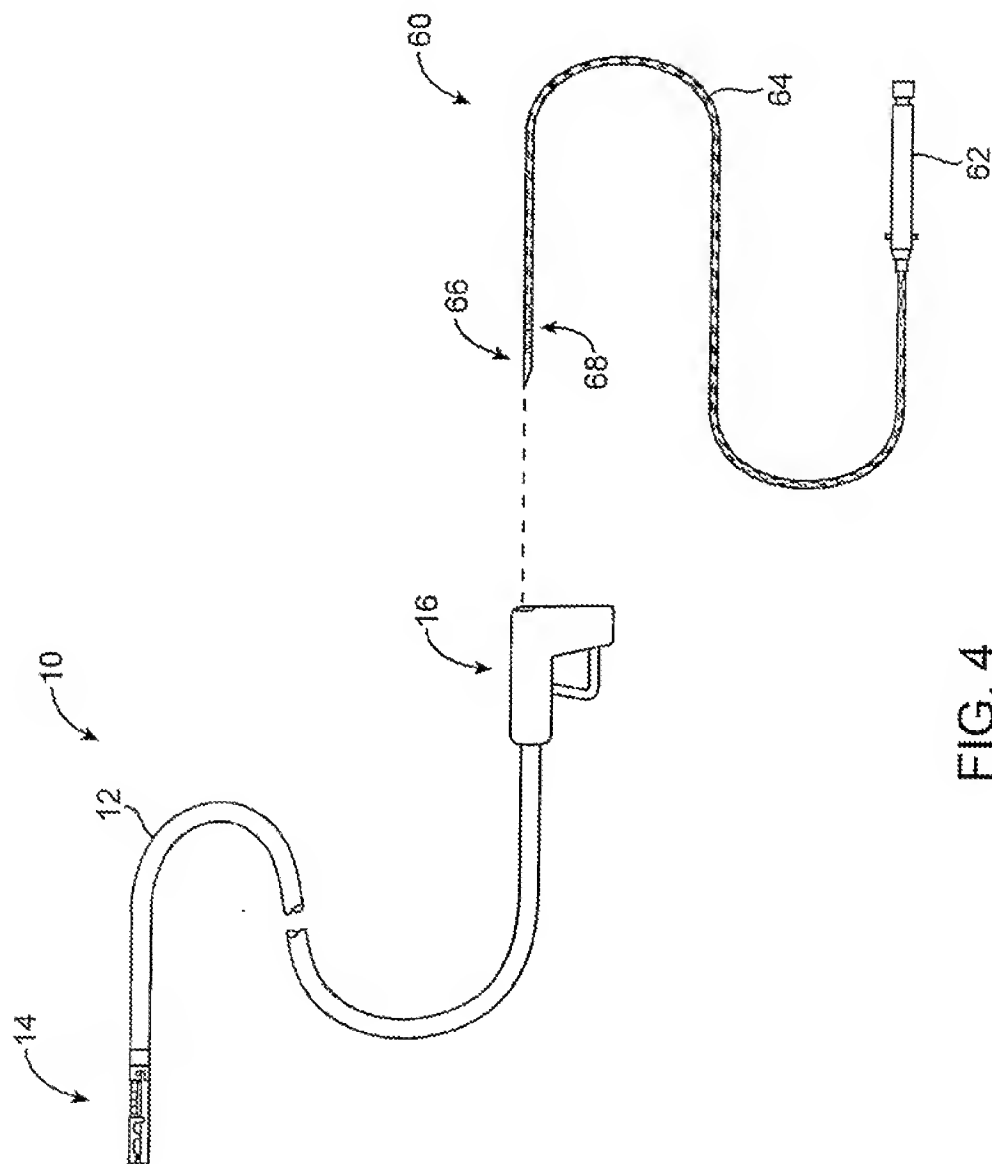


FIG. 4

5 / 12

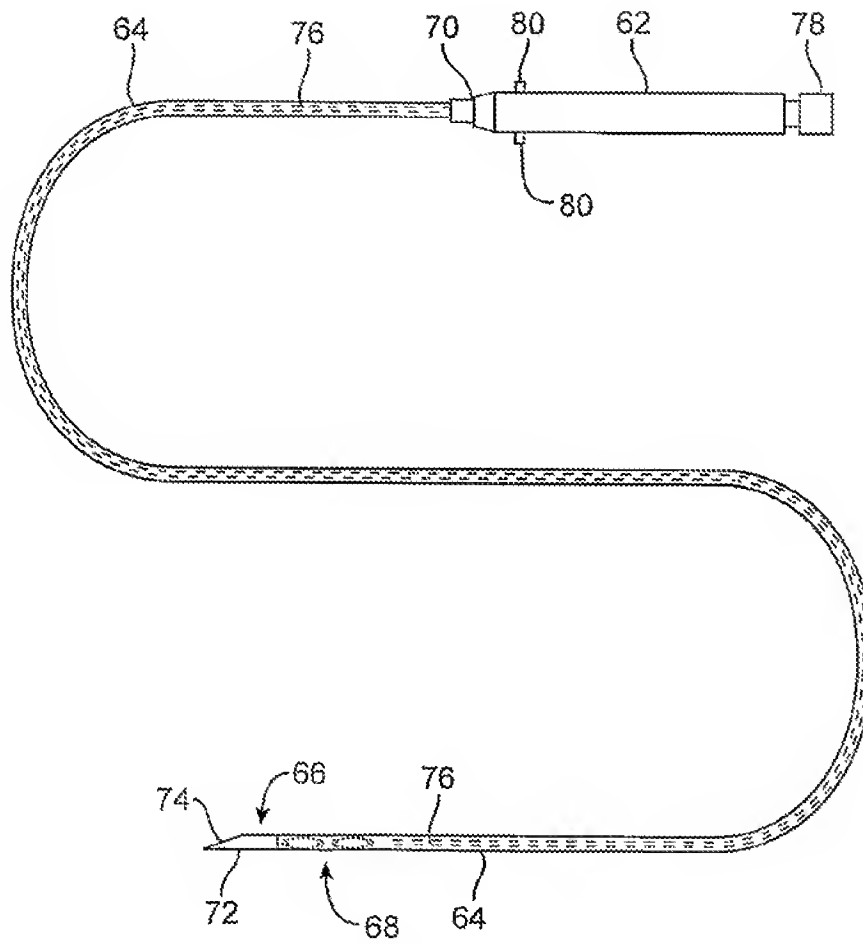


FIG. 5A

6 / 12

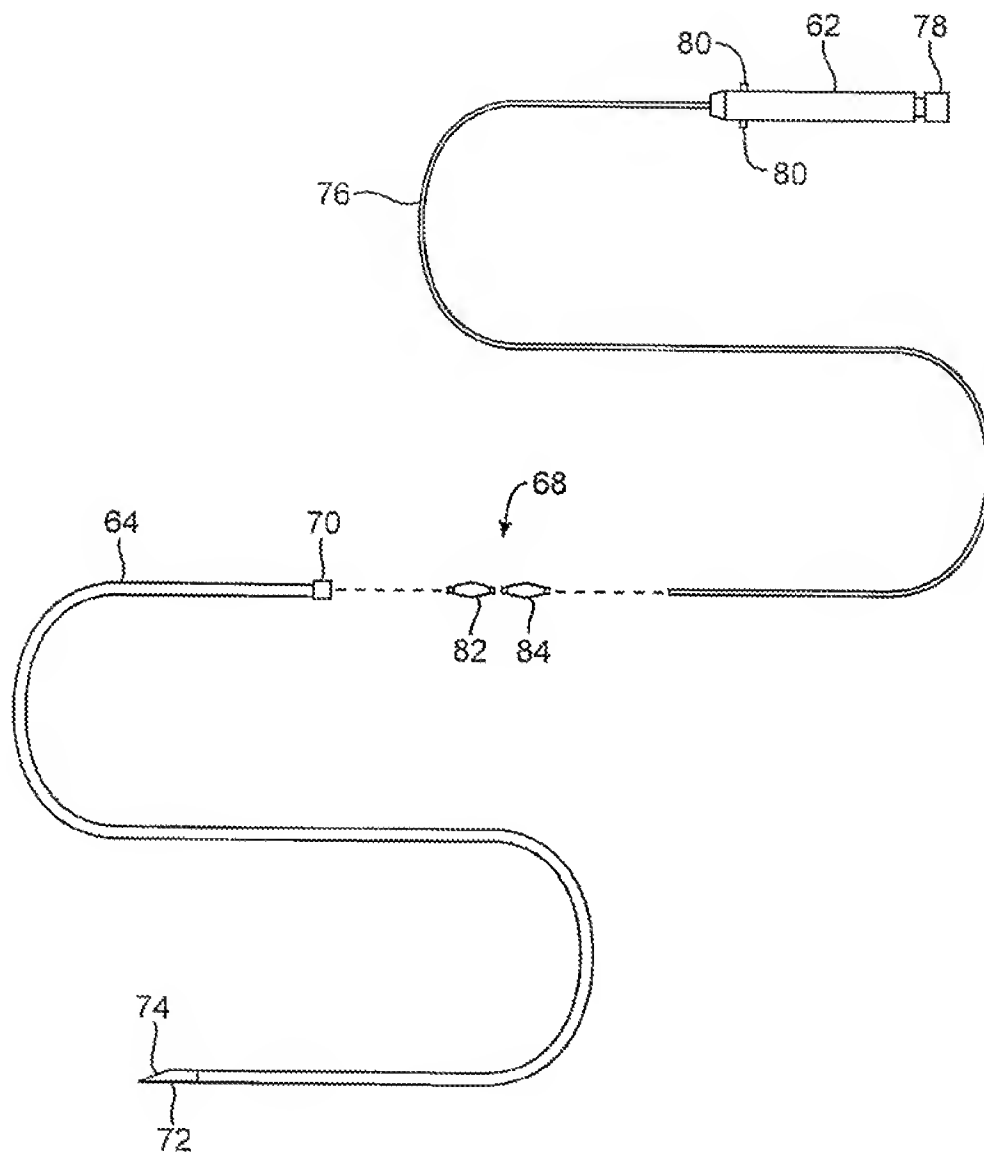


FIG. 5B

7 / 12

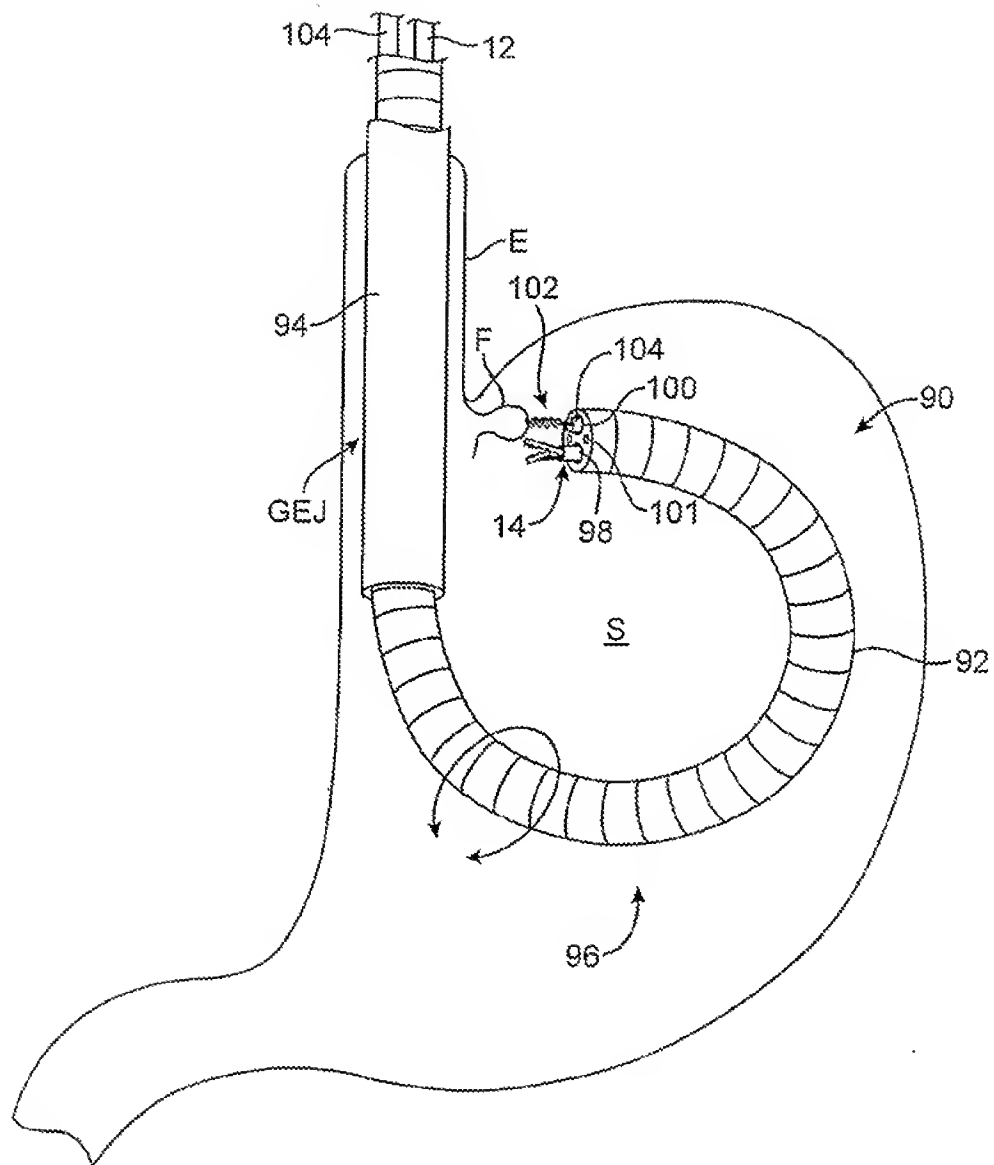


FIG. 6

8 / 12

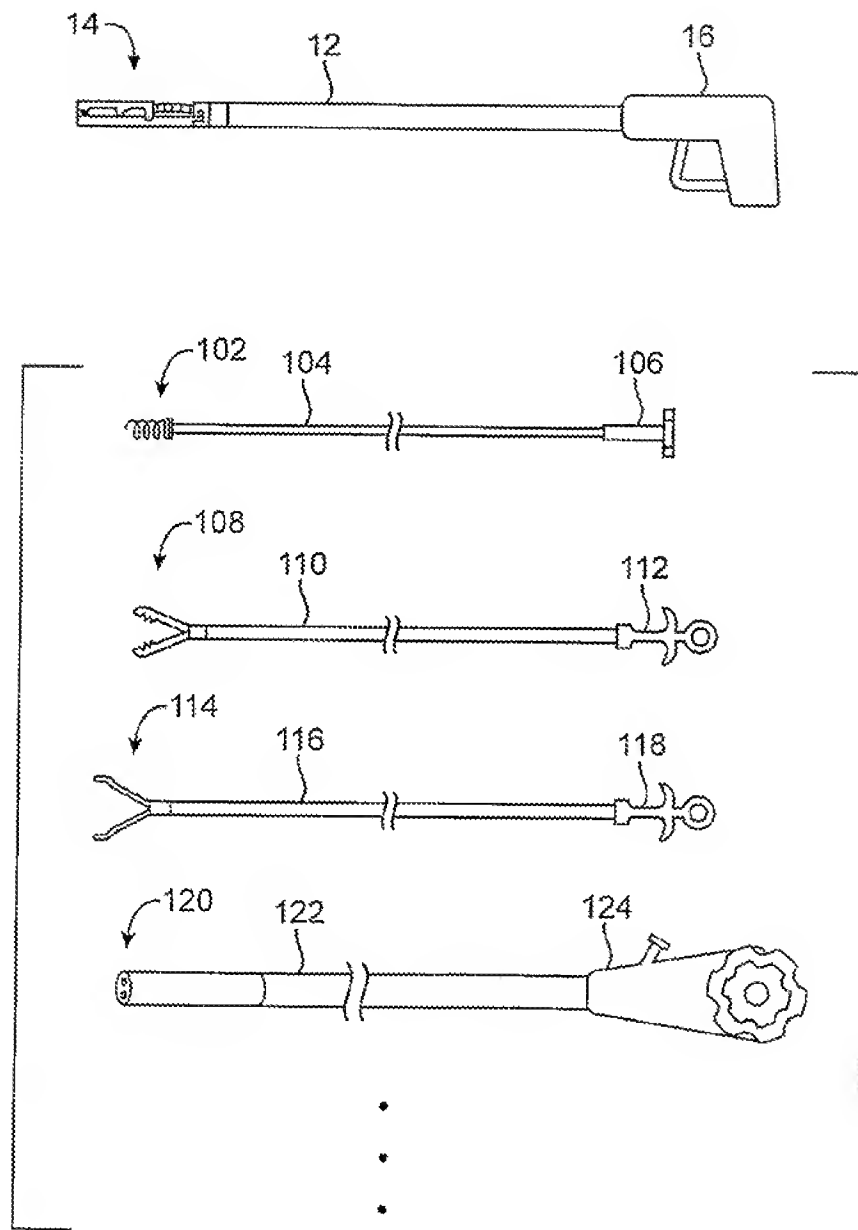


FIG. 7

9 / 12

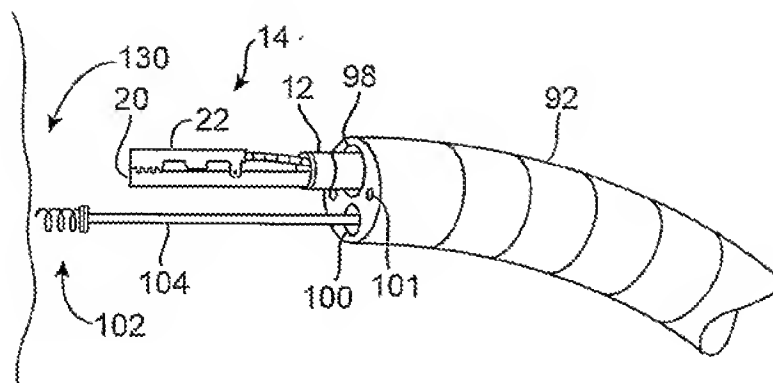


FIG. 8A

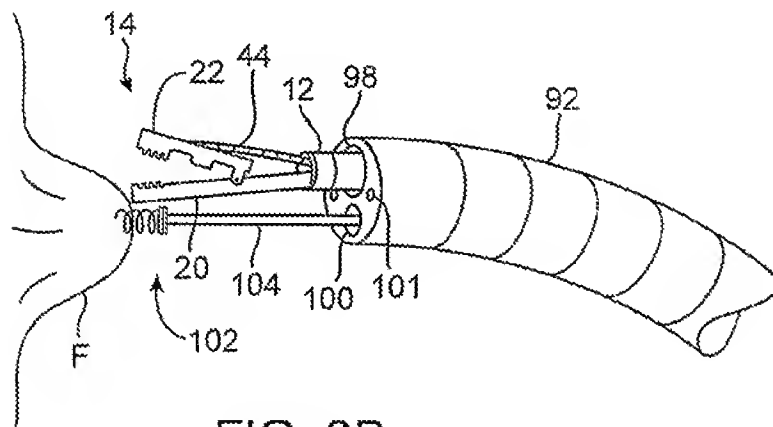


FIG. 8B

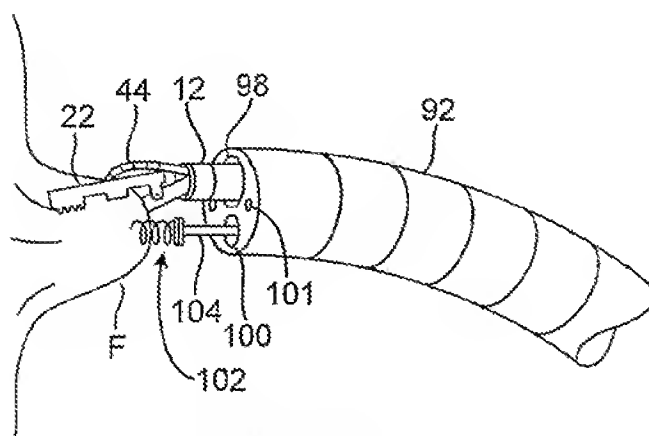


FIG. 8C

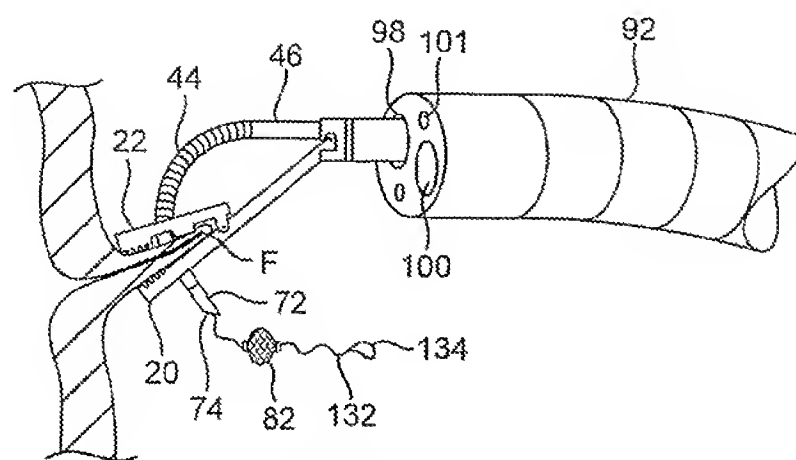


FIG. 8D

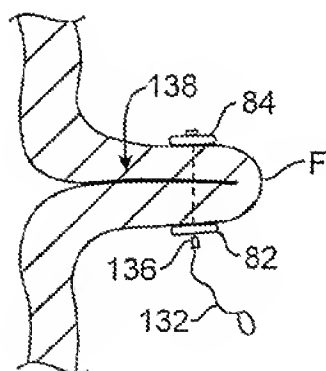


FIG. 9A

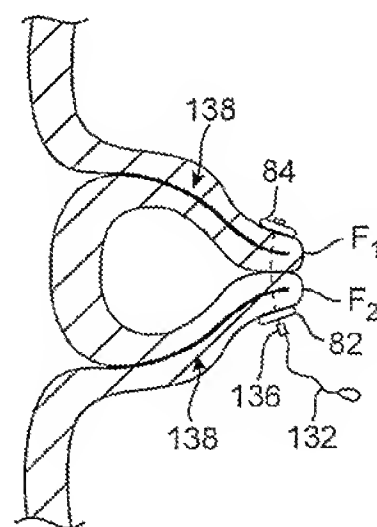
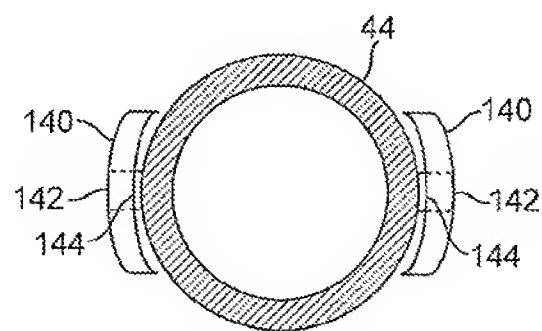
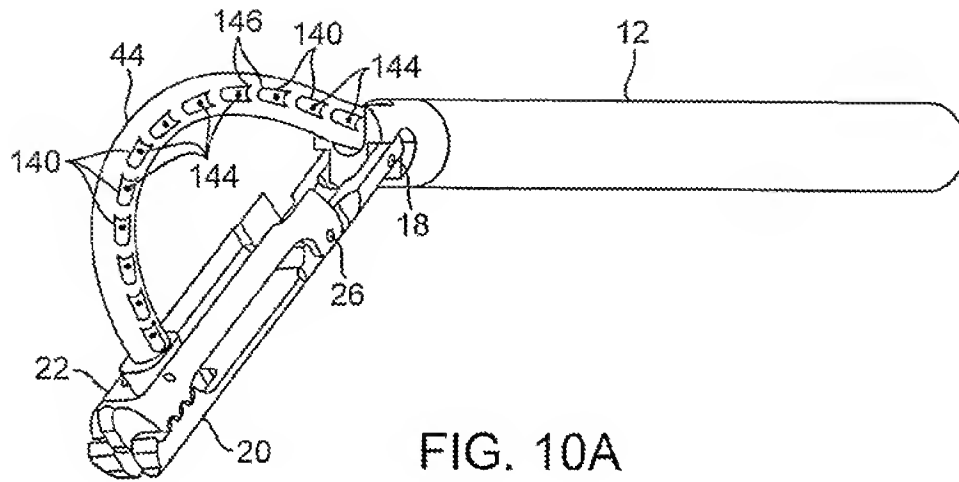


FIG. 9B





12 / 12

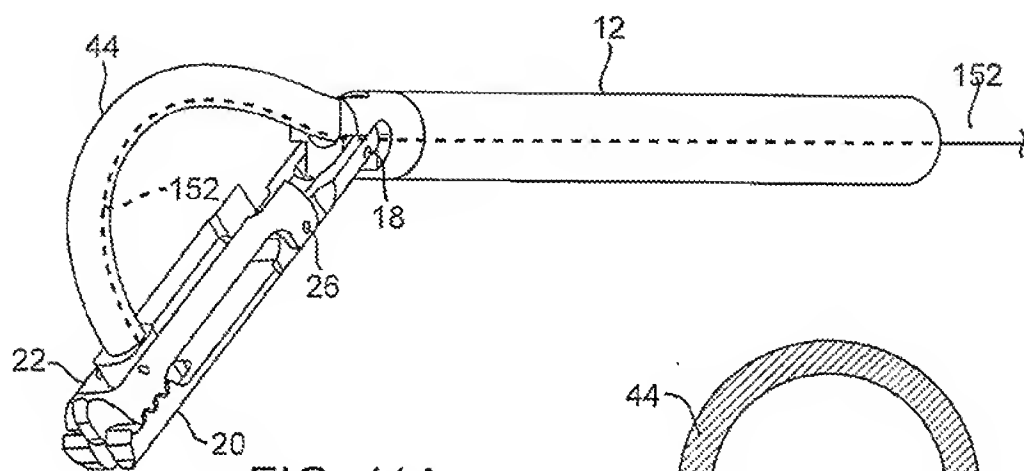


FIG. 11A

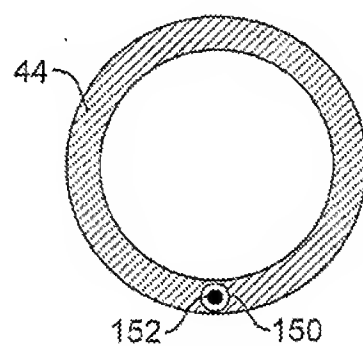


FIG. 11B

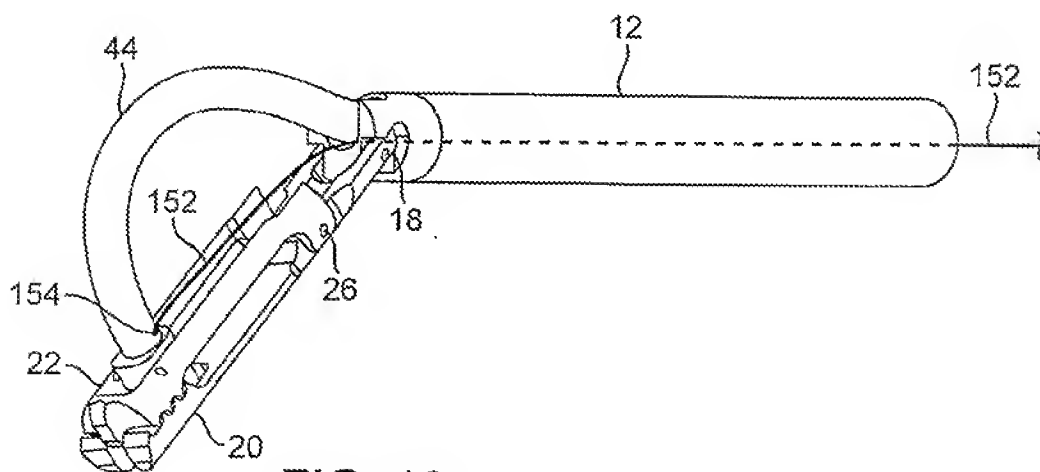


FIG. 12